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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,109	09/05/2000	Mathieu Hubertus Maria Noteborn	LEBV.008.01US	7279

24247 7590 10/07/2005

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/655,109	NOTEBORN ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/19/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *12-21,26-33,35 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 22-25 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed September 5, 2000, claims benefit to EPO applications: EP 99202858.9 filed September 2, 1999; and EP 99203465.2, filed October 21, 1999.

As indicated in the mailing July 27, 2005, the petition is **GRANTED** regarding the petition under 37 CFR 1 .137(b), filed July 19, 2005, to revive the above- identified application.

Applicants' amendment filed July 19, 2005 has been received and entered. The substitute specification has been entered. The new abstract has been entered. Claims 1-19, 21-28 and 31-33 have been amended. Claims 34-36 have been added. Claims 1-36 are pending.

Election/Restriction

Applicant's election with traverse of group I in the reply filed on July 19, 2005 is acknowledged. The traversal is on the ground(s) that the search should be co-extensive and not over-burdensome (see page 11 of Applicants' amendment). Further, it is argued that the method claims have also been amended to reflect their dependency on the products and should be rejoined as well (see page 11 of Applicants' amendment). This is not found persuasive because as evidenced by the classification of the inventions, the inventions are different and unique. The amendment to the claims are noted, however as a product by process the claims encompassing a protein are reasonably interpreted to be obtained from or made by different sources, again clearly indicating a difference in breadth of the search and considerations between the nucleic acids and

proteins as presently claimed. Applicants' arguments are not persuasive because the search and consideration for the restricted inventions are different, and would require an undue burden.

With respect to the method claims, it is noted that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.1 16; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product

claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 1-36 are pending. Newly added claim 34 is drawn to group I, and newly added claims 35-36 are drawn to group II. Claims 12-21, 26-33, 35 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 19, 2005. Claims 1-11, 22-25, and 34, drawn to an isolated nucleic acid encoding an apoptin- associating proteinaceous substance is presently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information

submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." See pages 27-30 of the substitute specification. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claim 22 is objected to because of the following informalities: Claim 22 includes embodiments drawn to a non-elected invention, specifically a protein product.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the term "hybridize" is considered indefinite because the metes and bounds would be determined by conditions that would vary among artisans. The relative term fails to clearly set forth the metes and bounds of the claims

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-11, 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcia *et al.* or deposit AF 101779 (EMBO June 1999-IDS reference).

The claims broadly encompass any nucleic acid sequence that encodes an apoptin-associating protein. Dependent claims set forth the origin of the sequence and/or functional properties. As acknowledged in the present specification (page 9) Garcia *et al.* teach RYBP, the homologue of AAP. Garcia *et al.* teach that RYBP was a cDNA and has the functional property of binding YY1. It is noted that the is no specific discussion on its ability to induce apoptosis under a variety of conditions, however it is maintained that this would be an inherent property of the sequence since it is the homologue of AAP and shares other functional properties as taught by Garcia *et al.* With respect to shared homology, there is no specific disclosure in the present specification of how this is calculated, therefor stretches of homology which are 100% homologous are considered to anticipate the claims. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441

F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claims 1-11, 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by deposit AI6277241 human YY1-Associated factor (EST- 23 April 1999).

The claims broadly encompass any nucleic acid sequence that encodes an apoptin-associating protein. Dependent claims set forth the origin of the sequence and/or functional properties. As indicated by the title AI6277241 is a cDNA termed human YY1-Associated factor, which is a homologue of AAP. Homology comparisons indicate that the specific sequences disclosed in the specification and AI6277241 share 99% homology. It is noted that the is no specific discussion on the function or specific ability to induce apoptosis under a variety of conditions, however it is maintained that this would be an inherent property of the sequence since it is the human homologue of AAP. The claims are broad and the instant specification does not teach specific sequences that must be present nor ones that can be changes and so given the high homology, it is maintained that AI6277241 (human YY1-Associated factor) shares the functional properties of the claimed sequences. With respect to shared homology, there is no specific disclosure in the present specification of how this is calculated, therefor stretches of homology which are 100% homologous are considered to anticipate the claims. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by

identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claims 1-11, 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by deposit US2003 0073623A1 (effective filing date of January 20, 1999).

The claims broadly encompass any nucleic acid sequence that encodes an apoptin-associating protein. Dependent claims set forth the origin of the sequence and/or functional properties. Homology comparisons indicate that the specific sequences disclosed in the specification and SEQ ID NO: 24859 share 96% homology. It is noted that the is no specific discussion on the function or specific ability to induce apoptosis under a variety of conditions, however it is maintained that this would be an inherent property of the sequence since it shares high homology to the specific SEQ ID NOs disclosed to be isolated AAP in the present specificaiton. The claims are broad and the instant specification does not teach specific sequences that must be present nor ones that can be changes and so given the high homology, it is maintained that SEQ ID NO: 24859 shares the functional properties of the claimed sequences. With respect to shared homology, there is no specific disclosure in the present specification of

how this is calculated, therefor stretches of homology which are 100% homologous are considered to anticipate the claims. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 22-25 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,809,189 B2. Although the conflicting claims are not identical, they are not patentably distinct

from each other because the species of AAP disclosed and claimed in '189 anticipates the instantly claimed product(s). In this case, the species anticipates the genus claims currently under examination.

Conclusion

No claim is allowed. Claim 34 is free of the art of record, because while the art discloses nucleic acid sequences and their respective putative encoded proteins, the art fails to specifically teach or make obvious SEQ ID NO: 6 required of claim 34.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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